



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR 12 2007

52 7 15 2007
Mr. Shan Chaudhuri
Regulatory Affairs Manager
Iovate Health Sciences U.S.A. Inc.
3880 Jeffrey Boulevard
Blasdell, New York 14219

Dear Mr. Chaudhuri:

This is in response to your letters of February 22, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Iovate Health Sciences U.S.A. Inc. is making the following claims, among others, for the products **Cholesterol MD** and **Allergy MD**:

Cholesterol MD

"Cholesterol MD is natural, drug-free solution with the clinically-proven power to lower cholesterol levels."

"[E]ffectively lowers LDL (bad) cholesterol levels and once you've reduced your cholesterol levels to an acceptable range, continuing to use Cholesterol MD also helps to maintain your newfound healthy cholesterol levels."

"100% Drug free powerful results."

Allergy MD

"100% Drug-free powerful results."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products, including the use of the terms "Cholesterol" and "Allergy" in the product names, suggest that they are intended to treat, prevent, or mitigate diseases (i.e., hypercholesterolemia and allergies) and intended as alternatives to drugs to treat these diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Vasilios Frankos". The signature is fluid and cursive, with the first name "Vasilios" written in a larger, more prominent script than the last name "Frankos".

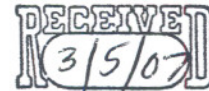
Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140



Feb 22, 2007

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT

Dear Sir or Madam:

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplement described below:

Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Blasdell, NY 14219

Name of Supplement: Cholesterol MD™

Statements of Nutritional Support:

1. Reduces cholesterol absorption from foods.
2. Use everyday to maintain healthy cholesterol levels.
3. Cholesterol MD is natural, drug-free solution with the clinically-proven power to lower cholesterol levels.
4. The unique Cholesterol MD formula effectively lowers LDL (bad) cholesterol levels and once you've reduced your cholesterol levels to an acceptable range, continuing to use Cholesterol MD also helps to maintain your newfound healthy cholesterol levels.
5. 100% Drug free powerful results.

To the best of my knowledge, the information contained in this notice is complete and accurate, and Iovate Health Sciences USA Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Shan Chaudhuri", written over a horizontal line.

Shan Chaudhuri
Regulatory Affairs Manager

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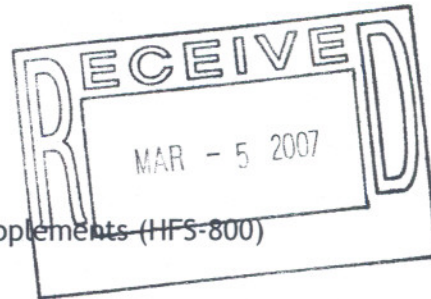
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Iovate Health Sciences U.S.A. Inc.
3880 Jeffrey Boulevard,
Blasdell, NY 14219

905.678.4052
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IOVATE

Feb 22, 2007



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Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Blasdell, NY 14219

Name of Supplement: Allergy MD™
Statements of Nutritional Support:

1. Clinically proven superior Immune System Support
2. Fast powerful results when you need it!
3. An all-in-one formula with a clinically proven compound scientifically designed to support your immune system in a totally new and powerful way!
4. Natural, immediate and long lasting effects.
5. 100% Drug-free powerful results.
6. Allergy MD is so effective because its key compound promotes the suppression of a specific immuno-active group of molecules known as "leukotrienes".
7. Allergy MD provides an unprecedented level of immune system support and helps the body suppress the effects of leukotrienes so you can be at your best.
8. In one key double-blind, placebo-controlled study, participant's demonstrated significant improvements in combating the physiological effects of numerous episode types and immune challenges.

To the best of my knowledge, the information contained in this notice is complete and accurate, and Iovate Health Sciences USA Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Shan Chaudhuri
Regulatory Affairs Manager

2007-1399